REMARKS

Favorable reconsideration of the subject application is respectfully requested in view of the above amendments and the following remarks. Claims 1-3, 9-11, and 13-30 are pending in the subject application, with currently amended Claim 1 being in independent format. With this Amendment and Reply, applicant submits a petition for a three-month Extension of Time, with the requisite fee, to extend the due date of the response to the Office Action, mailed August 24, 2004, from November 24, 2004 to February 24, 2005.

Applicant notes that the Examiner accepted applicant's transversal of the species election requirement of Claim 2 stated in applicant's response to election of species requirement dated April 26, 2004 and that the species election requirement is made final. Applicant also notes that Claims 1 (as amended in applicant's response to election of species requirement dated April 26, 2004) and 2-20 were examined.

The Examiner objects to the title of the invention on the basis that it is not descriptive and requires a new title to clearly indicate the invention to which the claims are directed. Applicant has amended the title to read: "Homeopathic Preparations of Purified Insulin-Like Growth Factor-1". Applicant respectfully submits that the amended title is clearly indicative of the invention to which the claims are directed.

Claim 1 has been amended to specify a preparation comprising a homeopathic potency of purified IGF-1 *suitable for oral administration*, wherein the concentration of the IGF-1 is less than a specified molar concentration. Preparations comprising a homeopathic potency of purified IGF-1 *suitable for oral administration* were previously claimed in dependent claim 4 and are described in the specification, as filed, for example, at pages 20-21. Claims 2, 3, 9-11, and 13-20 have been amended to conform to the terminology of amended claim 1. It is not believed that the term "preparation" has a different meaning from the term "composition", but the term "preparation" has been used to provide consistency with the title.

Claims 4-8 and 12 have been canceled. The subject matter of Claim 4 has been incorporated in Claim 1, as amended. Claims 5-8 and 12 have been canceled because they include subject matter that relates to delivery forms other than oral administration. It is noted that throat sprays are included in the subject matter of canceled Claim 5 and that applicant

considers such throat sprays to be a form of oral administration that would be encompassed by applicant's pending claims. It is also noted that the subject matter of Claims 5-8 and 12 is being canceled for purposes of expediency and ***not*** because applicant acquiesces in any of the Examiner's outstanding claim rejections. Applicant specifically cancels these claims without prejudice to applicant's ability to prosecute these or similar claims in related application(s).

Claims 21-30 have been added. New Claims 21-23 recite specific homeopathic potencies that were previously recited in the Markush group of Claim 13 and that are clearly described in the specification, as filed, at page 18. New Claims 24-26 recite homeopathic potencies of IGF-1, PDGF, and $TGF_{\beta 1}$, and support for new Claims 24-26 can be found in the paragraph beginning on page 14, line 23 and ending on page 15, line 6 of the specification as originally filed. New Claims 27-28 recite homeopathic potencies of IGF-1, GM-CSF, $PDGF_{BB}$, and $TGF_{\beta 1}$, and support for new Claims 27-28 can be found on page 14, lines 23-25 and page 17, lines 25-27 of the specification as originally filed. New Claim 29 recites an aqueous solution of a homeopathic potency of IGF-1, and support for new Claim 29 can be found on page 21, lines 4-9 of the specification as originally filed. New Claim 30 recites a homeopathic potency of IGF-1 in the form of a tablet, and support for new Claim 30 can be found on page 21, lines 18-19 of the specification as originally filed.

It is urged that support for all the above amendments may be found throughout the specification as originally filed and that none of the amendments constitute new matter. Claims 1-3, 9-11, and 13-30 are pending following entry of the above amendments.

Claim Rejection – 35 U.S.C. §112 , second paragraph

The Examiner has rejected Claims 13-18 under 35 U.S.C. §112, second paragraph, as being *indefinite* for failing to particularly point out and distinctly claim the subject matter which applicant regard as her invention. Specifically, the Examiner states that Claims 13, and 16-18 recite the limitation "C, X, and M" in the claims and suggested that the "C, X, and M" limitation be replaced by molar amounts. The Examiner states that Claim 14 is indefinite because the meets and bounds of "a homeopathic potency" are not clear. Further, the Examiner states that

Claims 15-18 are indefinite, improper, and incorrect composition claims because they are drawn to more than one composition in a singe composition claim.

Applicant's prior U.S. Patent No. 5,629,286 includes broad claims to compositions comprising a homeopathic dilution of one or more purified growth factors, with dependent Claims 5, 10, and 13 specifying that the concentration of the homeopathic dilution is between about 10^{-6} and $10^{-100,000}$ molar.

Applicant's prior U.S. Patent No. 6,239,105 recited a homeopathic preparation comprising purified growth hormone at a concentration of between about 1 x 10^{-6} molar and 1 x $10^{-100,000}$ molar in claim 1 and specifies various homeopathic potencies in the conventional "C", "X", and "M" designations in dependent claims 8, 9, 10, 14, and 19. Similarly, applicant's pending Claim 1 specifies a preparation comprising a homeopathic potency of IGF-1 of less than 1 x 10^{-6} molar. It is urged that the use of molar concentrations is appropriate in broad claims, such as these, to define the broad parameters of a homeopathic preparation. The use of molar concentrations is not, however, well-suited to define the narrower, specific homeopathic potencies specified in the pending claims. The potency designations used throughout the specification, as filed, and in the pending claims, are in accordance with well-established nomenclature that is well known to, and conventionally used by, one of ordinary skill in the art, as well as being generally accepted in the public domain by users of homeopathic products. The nomenclature may not be immediately intuitive to one trained in the classical allopathic health sciences. Therefore, applicant provides the following discussion and attaches several supporting documents to describe homeopathic potency designations and to support the homeopathic potencies set out in the pending claims.

The specification and claims employ standardized nomenclature to designate different homeopathic potencies. A key to understanding homeopathic potencies is that potency is not synonymous with dilution. Homeopathic potencies, also referred to as potency numbers, reflect the number of **dilutions and succussions** from the original mother tincture. There are three accepted methods for preparing homeopathic potencies, each having a separate designation.

The decimal scale uses the "X" designation and is based on 1 in 10 serial dilutions beginning with an initial 1/10 dilution of the mother tincture. This series of 1 in 10 serial

dilutions is designated as nX, where n is the fold dilution. For example, a 1/1,000,000 dilution (1 x 10^{-6}) is designated as a 6X potency (i.e., 1/10 x 1/10 x 1/10 x 1/10 x 1/10 x 1/10 with succussions between each successive dilution), a 15X potency is a 1/1,000,000,000,000,000 dilution (1x 10^{-15}), and so on.

The centesimal scale uses the "C" designation and is based upon 100-fold serial dilutions. This is the most commonly used nomenclature. A 2C potency is a 1/10,000 (1x 10^{-4}) dilution (i.e., 1/100 x 1/100), a 3C potency is a 1/1,000,000 (1x 10^{-6}) dilution (i.e., 1/100 x 1/100 x 1/100), etc.

The third accepted scale, the millesimal scale, uses the "m" designation and is based on 50,000-fold serial dilutions. For example, a 1m is a 1/50,000 dilution and a 2m is a 1/2,500,000,000 (1/50,000 x 1/50,000) dilution.

It has become standard practice in the art to adopt Roman numeral designations for certain potencies having large dilution factors. For example, a 1,000C potency is generally referred to as a 1M potency and a 10,000C potency may be denoted 10M. The capital M is distinguished from the "m" used to describe the millesimal system. Furthermore, this convention is also used to describe the millesimal system, such that a "1m" preparation is commonly denoted as a "LM" preparation.

As previously mentioned, potency is not the same as dilution. While there are overlaps in the three scales with regard to dilution, this does not necessarily mean equivalent dilutions have equivalent potencies. For example, 6X and 3C potencies may have the same dilution, i.e., 1x 10^{-6}, but the 6X potency has undergone 600 rounds of succussion, while the 3C potency has only undergone 300 rounds. Consequently, 6X and 3C potencies may exert different therapeutic effects. Simply put, the three different designations (i.e., X, C, and m) represent more than just different dilutions, and are actually three <u>different methods of preparing</u> homeopathic preparations that <u>yield different homeopathic potencies</u>. The "X" and "C" designations, and, to a lesser extent, the "M" designation are warranted to clearly distinguish the potency, not merely the dilution. Therefore, applicant respectfully maintains the specification and claims accurately and unambiguously describe the present invention.

Applicant submits that the nomenclature used in the specification and pending claims is

widely accepted in the art, and is definite and distinct as required by 35 U.S.C §112. The Examiner is invited to review relevant sections from the text "The Science of Homeopathy", which is of record and has been acted against applicant's pending claims. In particular, pages 164-167 provide a clear synopsis of the accepted nomenclature for homeopathic potencies and an explanation why dilution is not synonymous with potency. Additional support for the widely accepted nomenclature representing different preparation techniques may be found at pages 11-12 in "Homeopathy – A Frontier in Medical Science." Copies of relevant portions of these materials are attached for the Examiner's information.

Furthermore, applicant has provided documents to illustrate that the nomenclature used in the specification and claims is widely available and accepted in the public domain. Specifically, information pertaining to homeopathic potencies is widely available on the Internet and is routinely used in the labeling and marketing of homeopathic preparations, and most notably, for the labeling and marketing of homeopathic preparations of growth hormone. For example, an article found at www.medicinegarden.com ("Potencies by Debra LeRoy") describes the various potency designations and their derivation, and "Homeopathic LM Potencies – Homeopathic Pharmacy Terminology" found at www.alchemilla.com describes various potency symbols. As mentioned, homeopathic potency designations are routinely used to properly label commercial homeopathic products, which the general public must be familiar with in order to purchase the correct dosage or combination of dosages, as illustrated in the web pages downloaded for homeopathic remedies from Drugstore.com, Natural Living Products and Global Nutrition, Ltd. Selected materials from these Websites are attached for the Examiner's information.

Not only is the homeopathic nomenclature of the present specification and claims the accepted standard among homeopathic practitioners and the general public, but it is also recognized under the Federal Food, Drug and Cosmetic Act ("the Act"). The Act recognizes the official status of the standards provided in the Homeopathic Pharmacopeia of the United States, which describe homeopathic preparations (or homeopathic drugs) in terms of potencies as specified by dilution, such as 1X, 2X, etc., as described above. To faithfully adhere to the policy of the Act, applicant must properly label their product in homeopathic terms in order to avoid any

deceptive promotion and advertising (Section 502(b) of the Act and 27 CFR 201.10). The Examiner is invited to review the enclosed article *Homeopathic Drug Labeling and Advertising*, which describes the salient points of the Federal Food, Drug and Cosmetic Act as it pertains to homeopathic preparations.

The pending claims referring to specific homeopathic potencies further limit the broader recitation in Claim 1, which specifies a preparation comprising a homeopathic potency of purified insulin-like growth factor 1 (IGF-1) having a concentration of purified IGF-1 of less than 1×10^{-6} molar. Claim 1, by its terms refers to a molar concentration, while Claims 13, 16-18, 21-23. and 26, by their terms, refer to homeopathic potencies. It is clear from the claim language, and from the description of homeopathic potencies provided in the specification, that the terms 6X, 6C, 15X, 12C, 30C, 100C, 200C, and 1M refer to homeopathic potencies. One of ordinary skill in the art, and consumers of homeopathic products, know exactly what the homeopathic potencies mean.

Applicant emphasizes that the homeopathic potency designations in the pending claims is the most appropriate way to describe and define applicant's invention. Furthermore, the use of homeopathic designations that are in common use is required to put homeopathic practitioners, competitors and the general public on notice of potential infringement issues and to properly provide applicant with a basis in which to exclude others from making, using and selling the claimed compositions. In other words, using the homeopathic potency designations described in the specification and used in the art is required for the applicant to acquire meaningful, enforceable rights. Molar concentration designations are not utilized in the art and do not clearly and accurately describe the present invention. Therefore, applicant respectfully maintains the pending claims fully satisfy the requirements of 35 U.S.C. §112, second paragraph and the claim rejections may be properly withdrawn.

The Examiner states Claims 15-18 are improper composition claims because they are drawn to multiple compositions. The basis for this conclusion is premised upon the supposition that "the compositions are added together to form a single final composition having a final concentration as a single entity." Applicant respectfully suggests the Examiner may be unaware of a unique attribute of compositions comprising multiple homeopathic potencies. It is an

accepted principle in homeopathy that each homeopathic potency in a combination of potencies retains its unique "signature" in the carrier medium and combinations of potencies do not meld together to create a final potency. Applicant certainly appreciates the Examiner's argument that, in conventional science, combining *different dilutions of a like substance* would result in one final *dilution*. That principle, and therefore the Examiner's underlying supposition, however, does not apply in this instance. Combinations of *potencies* are not simply dilutions of a like substance. Rather, each individual potency in the combination retains its identity and exerts its individual effects. Therefore, it is an accepted practice in homeopathy to designate each potency of the combination in order for homeopathic practitioners to properly distinguish one combination from another. In addition, it is common practice in the marketplace to sell combinations of homeopathic preparations. Applicant has faithfully adhered to this accepted practice and has adopted established nomenclature to clearly and accurately claim combinations of multiple potencies. Therefore, applicant respectfully urges that claiming multiple homeopathic potencies in a preparation is acceptable. U.S. Patent No. 6,239,105 includes claims drawn to homeopathic preparations comprising multiple homeopathic potencies.

Applicant respectfully maintains the nomenclature used throughout the claims satisfies the requirements of 35 U.S.C. §112, second paragraph by particularly pointing out and distinctly claiming the subject matter of the present invention. Due to the nature of homeopathic potencies, applicant is compelled to use different potency designations to accurately describe the invention. To adopt one designation throughout the claims would be inaccurate, misleading and confusing to one of skill in the art and the general public.

Claim Rejection – 35 U.S.C. §112, first paragraph

The Examiner has rejected Claim 5 under 35 U.S.C. §112, first paragraph as lacking an enabling disclosure. Specifically, the Examiner states that the specification does not reasonably provide enablement for the administration of compositions containing IGF-1 to the throat, lungs, airways, nasal passages, eyes, and skin.

Claim 5 has been canceled and this rejection is therefore rendered moot. Applicant specifically does *not* acquiesce in this rejection and submits that the subject matter of Claim 5 was fully enabled by the specification and the level of skill in the art.

Claim Rejections – 35 U.S.C. §102(b)

Claims 1, 4-10, 12, and 14 are rejected under 35 U.S.C. §102(b) as being anticipated by *Antoniades et al.* (U.S. Patent No. 5,035,887). This rejection is respectfully traversed, particularly in view of the above amendments and the following remarks.

The Examiner alleges that *Antoniades et al.* describes using 500ng - 1μg of purified IGF-1 alone or in combination with PDGF for wound treatment. The Office is equating 500ng - 1μg to be less than 1 X 10^{-6}M based on a molecular weight for IGF-1 of 7.6KD. The Examiner further states that *Antoniades et al.* teaches the application of compositions in a biocompatible gel to the skin and describes 90% or greater purified IGF-1 and PDGF. This rejection is respectfully traversed.

Antoniades et al. teaches wound healing compositions having specified combinations of growth factors suspended in a carrier, such as a biocompatible gel, for topical application to a wound. PDGF, IL-1, and IGF-1 were tested alone, and in various combinations. In animal models, wounds treated with the combination of PDGF and IL-1 showed better healing than wounds treated with either growth factor alone. Similarly, wounds treated with the combination of IGF-1 and IL-1 showed better healing than wounds treated with either of those growth factors alone. The conclusion was that the combination treatments promote greater tissue growth and more rapid wound healing than would be predicted from the individual effects of the factors alone. (See, Col. 6, lines 2-8.)

Applicant's independent Claim 1 has been amended to specify that the homeopathic potency of purified IGF-1 is suitable for oral administration. *Antoniades et al.* is directed to wound healing compositions formulated for topical application to a wound. Applicant does not discern any teaching or suggestion in *Antoniades et al.* indicating that the wound healing compositions optionally containing IGF-1 may be used in an oral delivery format nor, it is urged,

would one of ordinary skill in the be led, by the teachings of *Antoniades et al*, to formulate a preparation comprising a homeopathic potency of purified IGF-1 suitable for oral administration.

It is therefore urged that applicant's pending claims are ***not*** anticipated by *Antoniades et al*, and that the rejection of the claims under 35 U.S.C. §102(b) must be withdrawn.

Claim Rejections – 35 U.S.C. §103(a)

Claims 13, and 15-18 are rejected under 35 U.S.C. §103(a) as being unpatentable over *Antoniades et al.*, in view of *Vithoulkas et al.* This rejection is respectfully traversed, particularly in view of the following remarks.

The teachings of *Antoniades et al.* and the deficiencies of *Antoniades et al.* with respect to applicant's claims are discussed above. *Vithoulkas et al.* describes standard protocols and nomenclatures for homeopathic potencies. *Vithoulkas et al.* does not overcome the deficiencies of *Antoniades et al.* with respect to applicant's claimed preparations. Applicant does not discern any teaching or suggestion in *Antoniades et al.* or *Vithoulkas et al.*, or any combination of those references, that would anticipate or render obvious applicant's claimed preparation comprising a homeopathic potency of purified IGF-1 suitable for oral administration.

Claims 2, 3, 11, and 20 are rejected under 35 U.S.C. §103(a) as being unpatentable over *Antoniades et al.*, in view of *Clark et al.* This rejection is respectfully traversed, particularly in view of the following remarks.

The teachings of *Antoniades et al.* and the deficiencies of *Antoniades et al.* with respect to applicant's claims are discussed above. *Clark et al.* discloses methods for treating obesity by administering an effective amount of growth hormone (GH) in combination with an effective amount of IGF-1. GH administration is by continuous infusion (using, e.g., an osmotic pump) or by injections more frequent than once a day and may be administered in a form in which it is bonded to a polymer. Similar administrations of IGF-1 are described. The dose for each component is on the order of micrograms to milligrams/kg body weight/day. These dosages are ***not*** at homeopathic potencies. Applicant also does not perceive that *Clark et al.* discloses or suggests oral administration of the combination. It is therefore urged that applicant's pending claims are not rendered obvious in view of this combination of references.

Claim 19 is rejected under 35 U.S.C. §103(a) as being unpatentable over *Antoniades et al.*, in view of *Whitson-Fischman* (U.S. Patent No. 5,162,037). This rejection is respectfully traversed.

The teachings of *Antoniades et al.* and the deficiencies of *Antoniades et al.* with respect to applicant's claims are discussed above. *Whitson-Fischman* discloses magnetizing homeopathic mixtures of herbs, herbal extracts and other compounds and administering such homeopathic medicaments through selected acupuncture points. Various delivery forms of homeopathic preparations are described. Applicant does not perceive that *Whitson-Fischman* discloses or suggests the use of homeopathic potencies of purified IGF-1 or other purified growth factors. *Whitson-Fischman*, rather, discloses the use of more conventional herb-based homeopathic medicaments.

It is urged that *Whitson-Fischman* does not overcome the deficiencies of *Antoniades et al.* with respect to applicant's pending claims and that no combination of the references relied upon for rejection renders applicant's claimed preparations obvious in the manner required by 35 U.S.C. §103(a).

Claim Rejections – Double Patenting

The Examiner has rejected Claims 1-20 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claims 1-13 of U.S. Patent No. 5,629,286. Applicant is the owner of U.S. Patent No. 5,629,286. Applicant is filing, herewith, a terminal disclaimer for U.S. Patent No. 5,629,286 in accordance with 37 CFR 1.321(c) to overcome the double patenting rejections.

The Examiner has also rejected Claims 1-20 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claims 1-19 of U.S. Patent No. 6,239,105. Applicant is also the owner of U.S. Patent No. 6,239,105. Applicant traverses this rejection.

The composition claims of the '105 patent are directed to homeopathic preparations of purified growth hormone. Claim 6 is directed to a method for modulating IGF-1 levels in serum of a patient comprising administering a homeopathic preparation of purified growth hormone.

Applicant's pending claims are directed to preparations comprising a homeopathic potency of purified insulin-like growth factor-1 (IGF-1). It is urged that the presently claimed preparations comprising a homeopathic potency of purified IGF-1 are ***not*** obvious in view of the previously patented homeopathic preparations of purified growth hormone.

Conclusion

In view of the above amendments and remarks, applicant believes that she has addressed all of Examiner's concerns and that all of the pending claims are now in condition for allowance. Early consideration and allowance of all the pending claims is respectfully requested.

Respectfully submitted,

By: _____
Ann W. Speckman
Registration No. 31,881

Date: February 24, 2005

SPECKMAN LAW GROUP PLLC

20601